REMARKS

Claims 1, 2, 4-9 and 11-25 are pending in the application. Claims 1, 2, 4-9 and 11-25 have been rejected. No claims have been allowed.

Claims 1, 16 and 18 have been amended to more clearly describe and distinctly claim the subject matter the Applicants consider their invention. Specifically, claims 1, 16 and 18 have been amended to incorporate the subject matter of dependent claims 2, 17 and 19, respectively. Accordingly, claims 2, 17 and 19 have been cancelled. No new matter has been introduced by this amendment.

Claims 1, 4-9, 11-16, 18, and 20-25 are presented for further consideration. Reconsideration of the claim rejections and allowance of the pending claims in view of the following remarks are respectfully requested.

Claim Rejections – 35 U.S.C. § 103

Claims 1, 2, 4-9, 11 and 25 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Gibbs (USPN 5,085,649; "Gibbs"), Capes (USPN 6,217,550; "Capes"), or Rosoff et al. (US 20020091361 A1; "Rosoff") in view of Newby et al. (USPN 6,298,541; "Newby"). According to the Examiner, Gibbs, Capes and Rosoff each disclose a single use syringe with a barrel, a needle cannula, a plunger with an elongated body having a proximal portion, a distal portion and a stopper slidably positioned in fluid-tight engagement with said inside surface of said barrel for drawing fluid into and driving fluid out of said chamber by movement of said stopper relative to said barrel, said elongate body portion extending outwardly from said open proximal end of said barrel, wherein the plunger breaks upon excessive force.

The Examiner acknowledges that Gibbs, Capes and Rosoff fail to disclose an elongated needle shield, but asserts that Newby discloses an elongate needle shield hingedly

connected to said barrel, said needle shield having two side walls defining a longitudinal opening and a back wall between said side walls defining a recess having an interior surface, said needle shield capable of pivoting from an open position wherein said needle cannula is exposed, to a closed needle protecting position wherein said distal end of said needle cannula is within said longitudinal opening of said shield to prevent reuse of the needle.

Thus, according to the Examiner, it would have been obvious for one of ordinary skill in the art to combine the device of Gibbs, Capes or Rosoff with the teachings of Newby because Newby discloses a shield that prevents accidental pricking prior to, and after using, the needle device.

Claims 2, 17 and 19 have been cancelled, rendering the rejection with regard to these claims moot. With regard to claims 1, 4-9, 11-16, 18, and 20-25, Applicants respectfully traverse these bases for rejection.

The standards for making an obviousness rejection are summarized in MPEP § 706.02(j) as follows:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck,* 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

In rejecting claims under 35 U.S.C. § 103, it is incumbent upon the Examiner to establish a factual basis to support the legal conclusion of obviousness. *See In re Fine*, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). In so doing, the Examiner must make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148

USPQ 459, 467 (1966), *viz.*, (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; and (3) the level of ordinary skill in the art. "[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Although the analysis need not identify explicit teachings directed to the claimed subject matter, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385, 1396 (2007). As such, "'there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)).

Claims 1, 4-9, 11-16, 18, and 20-25 are each directed to a single use syringe assembly comprising, *inter alia*, 1) a barrel including a cylindrical side wall whose inside surface has a discontinuity, and a plunger including an elongate body portion having a contractible portion, and a discontinuity, such that when an additional distally directed force is applied to the plunger after fluid has been delivered from the barrel, the plunger shortens at the contractible portion so that the plunger discontinuity moves distally to engage the barrel discontinuity to lock the plunger in the barrel; 2) at least one break point on the plunger for allowing it to break upon application of an excessive force intended to move the plunger proximally after it has been locked to the barrel; and 3) an elongate needle shield hingedly connected to the barrel and capable of pivoting from an open position wherein the needle cannula is exposed to a closed needle protecting position.

In the embodiment shown in Figure 1 of the instant specification, the discontinuity of the barrel is shown as locking projection 45, while the contractible portion and the

discontinuity of the plunger are shown as flexing elements 57 and annular locking ring 58, respectively. As shown in Figure 11, upon completion of the injection, an additional axial force in the distal direction indicated as C is applied to the proximal portion of the plunger, causing flexing portions 57 to flex inwardly, and further causing locking ring 58 on the plunger to advance distally in the barrel past locking projection 45 on the barrel. In this way, the plunger is locked in the barrel and the syringe is disabled and unusable. Any attempt to withdraw the plunger from the barrel in the proximal direction will result in the proximal portion of the plunger breaking off at breaking points 62, as shown in Figure 12. After the syringe has been disabled, the safety shield 28 may be activated by application of a force in the direction of arrow D, as shown in Figure 12, to shield the needle cannula and protect against accidental needle sticks.

As discussed more fully below, none of the references cited by the Examiner, either alone or in combination, teaches or suggests this combination of elements for disabling a syringe.

Rejection over Gibbs in view of Newby

The portions of Gibbs relied upon by the Examiner (Figure 12 and 32 and accompanying text) disclose a mechanism for disabling a syringe based on needle retraction. As shown in Figures 8-12 of Gibbs, a hollow needle 93 is releasably held by molded plastic or structural adhesive attachment in a forward needle hub 94. After completion of fluid injection, the end of the needle within the syringe barrel 61 punctures an elastomeric diaphragm seal 92 and is captured in a metal stamping 89. Piston frame sections 84 and 86 are restrained by the end of the syringe barrel 61, while shearing of the breaking tabs 87 and 88 (Figure 6) allows the needle capture nub 78 to move forward relative to the piston frame and distend the elastomeric diaphragm seal. Further movement of the plunger 60 into the

barrel causes the needle end to forcibly encounter the plastic needle capture nub. Upon needle impact with the nub 78, further sequential movement causes pry tabs 95 to be restrained by the piston frame sections 84 and 86, transmitting the restraining forces longitudinally through intermediate member 66 to breaking tabs 67 (Figure 6). Further movement of the plunger 60 into the barrel causes the tabs 67 to break, thus allowing the intermediate member to slide between spaced members 64 and 65. As fingers 73 and 74 move forward, reversible supports 76 and 77 deform. The finger tips are deflected towards needle capture nub pry tabs 95 by concave details of the piston frame sections, thereby providing initial retraction force which removes the needle 93 rearward of its releasable attached position within the hub 94. When reversing support joints 79, 82, 83 and 81 pass a position opposite each other, a spring "over-center" mechanism results whereby the reversing supports in effort to return to their pre-stressed and relatively straight length, apply a backward force to the needle capture nub which begins to move backward from the piston frame sections. The reversible supports have a resilient tendency to straighten out to their natural position, which forces the needle capture nub backward to where the needle 93 is fully retracted. (Gibbs, col. 5, line 49 to col. 6, line 23.)

Similarly, as shown in Figure 26-32 of Gibbs, the plunger 132 of needle assembly 131 is pushed forward in the barrel 137 to expel the fluid therein. Continued forward movement of the plunger causes forcible separation of the mating detents between needle capture nub 149 and piston frame 134 (Figure 25), allowing the needle capture nub to extend forward of the restrained piston frame, thereby stretching piston diaphragm 136, and causing the diaphragm to be pierced by the end of needle 154. The needle capture nub extends into well 153 and grips the end of the needle. This forward thrust produces impact that breaks a brittle type of adhesive which maintains the needle in needle hub portion 156. Further forward

movement of the plunger causes leading edges 143 and 144 of the reversible supports to engage the concave rear surface of the piston frame, and begin rearward travel until the free ends contact the underside of platform 146. Continued forward movement of the plunger causes breaking tabs 147 and 148 to break, and causes the reversible support leading ends 143 and 144 to move backwardly in a longitudinal direction opposite reversible supports 141 and 142, thereby prying the platform 146 from its resting place in the plunger and the needle capture nub 149 from piston frame 134. Thereafter, the coil spring 133 exerts a backward force on the platform, retracting the needle capture nub and needle. Barbs 139 interlock in the barrel recess 152 to lock the plunger within the barrel. (Gibbs, col. 8, line 64 to column 9, line 27.)

Thus, contrary to the Office Action, the cited portions of Gibbs does not disclose a plunger having at least one break point for allowing it to break upon application of an excessive force intended to move the plunger proximally after it has been locked to the barrel. Although Figure 32 of Gibbs does show the plunger locked within the barrel of the syringe, breakage of breakage tabs 147 and 148 has already occurred during movement of the plunger in the distal direction. Once locked in the barrel, there is no break point left on the plunger that would prevent its movement in the proximal direction if an excessive force was applied. Clearly, the remaining portion of the plunger with its attached needle shown in Figure 32 could be withdrawn from the barrel *in toto* using a force sufficient to overcome the disclosed locking mechanism. As such, Gibbs fails to teach or suggest the claimed plunger break point, and thus cannot render the claimed subject matter obvious, even in combination with the safety shield disclosed in Newby. *See* MPEP § 2143.03.

Furthermore, notwithstanding Gibbs' failure to teach or suggest the claimed plunger break point, common sense dictates that one skilled in the art would not have reasonably

looked to combine Gibbs and Newby in the manner asserted by the Examiner. *See KSR*, 127 S. Ct. 1727, 82 USPQ2d at 1397 ("Rigid preventative rules that deny fact finders recourse to common sense . . . are neither necessary under our case law nor consistent with it."). Clearly, there is no benefit of adding a safety shield, such as disclosed in Newby, to the needle assembly disclosed in Gibbs, which already provides a mechanism for needle shielding to prevent accidental needle sticks, namely needle retraction. *See Ex parte Rinkevich*, Appeal No. 2007-1317 (BPAI 2007) ("In the instant case, we conclude that a person of ordinary skill in the art *having common sense* at the time of the invention would not have reasonably looked to Wu to solve a problem already solved by Savill. Therefore, we agree with Appellants that the Examiner has impermissibly used the instant claims as a guide or roadmap in formulating the rejection."); *Ex parte Green*, Appeal No. 2007-1271 (BPAI 2007) ("Here, we agree with Appellant that a person of ordinary skill in the art would not have reasonably looked to Somashekar to provide a server capability that was already provided by Kuwata. In the record before us, we find only the language of the instant claims suggest such a combination . . . . Therefore, we conclude that an artisan *having common sense* at the time of the invention would not have reasonably considered embedding a server within an existing server in the manner suggested by the Examiner.").

Accordingly, Applicants submit the Examiner has failed to make out a *prima facie* case of obviousness of claims 1, 4-9, 11-16, 18, and 20-25 over Gibbs in view of Newby, and reconsideration of this basis for rejection is respectfully requested.

Rejection over Capes in view of Newby

The portions of Capes relied upon by the Examiner (Figure 19 and accompanying text) disclose a mechanism for disabling a syringe involving a breakable plunger. As shown in Figures 17-20, syringe 620 comprises barrel 621 having a fluid chamber 623, a proximal

end 625, a distal end 627 and an elongated tip 628 extending from the distal end and having a passageway 629 therethrough in fluid communication with the chamber. A collar 631 surrounds the tip. A needle assembly 640 includes a cannula 641 having a proximal end 643, a distal end 644 and a lumen therethrough. A hub 647 includes an open proximal end 649 with a cavity therein, and a distal end 651 joined to the proximal end of the cannula so that the lumen is in fluid communication with the cavity of the hub. The hub further includes an outside surface 652. The needle assembly is connected to the barrel so that the elongated tip of the barrel is in the cavity of the hub and the outside surface of the hub is adjacent to the one or more locking tabs so that the locking tabs prevent removal of the needle assembly from the barrel through contact between the locking tab and the outside surface of the hub. A plurality of locking tabs 634 projects radially inwardly from the collar 631 to allow the attachment of the needle assembly to the barrel through axial motion of the hub toward the barrel. A plunger 659 includes an elongated plunger rod 661 having a longitudinal axis 662, a proximal portion 663 and a distal portion 664 connected by a breakable connection 668. Specifically, proximal portion 663 includes a distal projection 669 having four transverse protuberances 670, which are connected to distal portion 664 by breakable connection 671. Distal portion 664 includes a stopper 665 slidably positioned in fluid-tight engagement with an inside surface 622 of the chamber for drawing fluid in and out of the chamber by movement of the plunger relative to the barrel. Upon completion of an injection with the needle assembly, the user can apply an additional force indicated as A in Figure 19, to the proximal portion. Force A is sufficient to break the breakable connections 671, which causes the plunger rod to separate into two or more unusable pieces, as shown in Figure 20. (Capes, col. 9, line 41 to col. 42.)

Thus, the portions of Capes relied upon by the Examiner teach only a breakable plunger as a disabling mechanism. The Examiner has not pointed to any part of Capes that teaches or suggests a syringe barrel having a discontinuity, and a plunger having a contractible portion and a discontinuity, such that when an additional distally directed force is applied to the plunger after fluid has been delivered from the barrel, the plunger shortens at the contractible portion such that the plunger discontinuity moves distally to engage the barrel discontinuity to lock the plunger in the barrel, as recited in the instant claims. Indeed, Capes specifically states that the embodiment of Figures 17-20 is a significant advance over single-use syringes of the prior art because "it allows multiple strokes of the plunger with respect to the barrel without automatically locking and rendering the syringe unusable[, and] also allows the plunger to move to its distal-most position inside the barrel without automatically locking the plunger to the barrel." (Capes, col. 11, lines 53-59) (emphasis added.) As such, Capes teaches away from a barrel locking mechanism such as the one recited in the instant claims, and thus cannot render the claimed subject matter obvious, even in combination with the safety shield disclosed in Newby. *See* MPEP § 2145.

Accordingly, Applicants submit the Examiner has failed to make out a *prima facie* case of obviousness of claims 1, 4-9, 11-16, 18, and 20-25 over Capes in view of Newby, and reconsideration of this basis for rejection is respectfully requested.

Rejection over Rosoff in view of Newby

The portions of Rosoff relied upon by the Examiner (Figures 1-3 and accompanying text) disclose a multiple dose syringe comprising a fluid container inside a syringe barrel. As shown in Figures 1-3, syringe 10 includes a cylindrical hollow barrel 12 with a closed end 14 and an open end 16. The cylindrical walls of the barrel define a cavity 18, which is adapted to receive and hold the fluid to be dispensed. The closed end has an injection port 22 which

is configured to receive a needle 24. A fluid container 28 is slidably received into barrel 12 through open end 16. The container includes a cylindrical bellows-like shell 30. The shell is preferably made of a flexible material that is non-reactive to the fluid stored therein (e.g., saline). The flexible material allows the container to collapse to dispense fluid. A connector 32 is formed on the closed end of the shell (Figure 5). Connector 32 is joined by a coupler 34 to corresponding connector 36 formed on the end of a plunger 38. The end of the shell opposite connector 32 includes a passage 42 that is selectively sealed by a closure member in the form of a cap 44 (Figure 6). The shell includes a circumferential groove 46 that receives a corresponding flange 48 formed on the inside surface of the cap. The outer perimeter of the cap is shaped to form a perimeter seal 50 and sized to fit snuggly within the barrel, similar to the tip on a standard plunger. When the container is placed in the barrel, the perimeter seal effectively separates the barrel into two regions or cavities: a first region 52 disposed between the closed end and the cap and a second region 54 disposed behind the cap and occupied by the container. An inwardly facing cup 56 is formed on the end face of the cap. The walls of the cup are received in a recess 58 formed in the end of the shell proximal to passage 42. The bottom of the cup forms a rupture zone 60 that is pressure rupturable, i.e. ruptures when fluid pressure across the rupture zone exceeds some desired level. An operator selects a syringe whose fluid container 28 is pre-loaded with saline package and attaches a needle to barrel 12. The operator then loads the desired amount of medicine into the syringe similar to loading a conventional syringe. The needle is then inserted into the patient or an IV, and the medicine is dispensed by depressing the plunger 38. When the medicine is dispensed, subsequent pressure on the plunger causes the cap 44 to open by rupturing rupture zone 60, thereby releasing the saline. The plunger is then further depressed to compress the container, and

force the secondary fluid out, thereby flushing the medicine. (Rosoff, page 1, ¶ 0019 to page 2, ¶ 0024; page 3, ¶ 0032.)

Thus, the portions of Rosoff relied upon by the Examiner teach only a multiple dose syringe comprising a fluid container inside a syringe barrel, wherein the plunger expels fluid out of both the barrel and the fluid container. The Examiner has not pointed to any part of Rosoff that teaches or suggests a syringe barrel having a discontinuity, and a plunger having a contractible portion and a discontinuity, such that when an additional distally directed force is applied to the plunger after fluid has been delivered from the barrel, the plunger shortens at the contractible portion such that the plunger discontinuity moves distally to engage the barrel discontinuity to lock the plunger in the barrel, as recited in the instant claims. Nor has the Examiner identified a teaching or suggestion in Rosoff of a plunger break point that allows the plunger to break upon application of an excessive force intended to move the plunger proximally after it has been locked to the barrel. In fact, Rosoff does not disclose any mechanism for disabling a syringe after fluid delivery. As such, Rosoff cannot render the claimed subject matter obvious, even in combination with the safety shield disclosed in Newby. *See* MPEP § 2143.03.

Accordingly, Applicants submit the Examiner has failed to make out a *prima facie* case of obviousness of claims 1, 4-9, 11-16, 18, and 20-25 over Rosoff in view of Newby, and reconsideration of this basis for rejection is respectfully requested.

CONCLUSION

It is believed that claims 1, 4-9, 11-16, 18, and 20-25 are now in condition for allowance, early notice of which would be appreciated. No additional fees other than for the 3-month extension of time are believed due at this time. If, however, there are any additional charges due in connection with this paper, the Examiner is authorized to charge Deposit Account No. 02-1666. Please contact the undersigned if any further issues remain to be addressed in connection with this submission.

Respectfully submitted,

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